

MAY - 5 2008

## 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) Number is:

K073454

### 1. Applicant Device Information

**Trade/Proprietary Name:** Pulse Oximeter CMS-50C

**Common Name:** Oximeter

**Classification Name:** Oximeter

**Device Class:** II

**Product Code:** DQA

**Regulation Number:** 870.2700

**Review Panel:** Anesthesiology

**Intended Use:**

Pulse Oximeter CMS-50C is a non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patient at home, and hospital (including clinical use in internist/surgery, Anesthesia, intensive care and etc). Not for continuously monitoring.

### 2. Submitter Information

**Manufacturer Name:**

Contec Medical System Co., LTD.

No.2-1 Hengshan Road, Economic and Technical Development Zone

Qinghuangdao , Hebei,China, 066000

**Contact Person of the Submission:**

Ms. Diana Hong

Mr. Eric Chen

Shanghai Mid-Link Business Consulting Co., Ltd

Suite 8D, Zhongxin Zhongshan Mansion,

No.19, Lane 999, Zhong Shan Nan Er Road

Shanghai, China 20020

**Phone:** +86-21-64264467 x 152

**Fax:** +86-21-64264468 x 809

**Email:** [Diana.hong@mid-link.net](mailto:Diana.hong@mid-link.net)

[eric.chen@mid-link.net](mailto:eric.chen@mid-link.net)

### 3. Predicate Device

Fingertip pulse Oximeter MD300C (K070371)

**K-number:** K070371

**Product Code:** DQA

**Intended Use:**

Fingertip Pulse Oximeter MD300C is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate of adult and pediatric patient at home, and hospital (including clinical use in internist/surgery, Anesthesia, intensive care and etc). Not for continuously monitoring.

**Manufactured by:**

Beijing Choice Electronic Technology Co., Ltd.

Bailangyuan Building B 1126-1127, Fuxing Road A36,

Beijing , P.R.China, 100039

### 4. Device Description

The pulse oxygen saturation is the percentage of HbO<sub>2</sub> in the total Hb in the blood, so-called the O<sub>2</sub> concentration in the blood. It is an important bio-parameter for the respiration. Many of the respiration disease will cause hypoxemia, even damage the patient's life. As a result, monitoring the SpO<sub>2</sub> is indispensable in the clinical rescuing. The traditional method to measure SpO<sub>2</sub> is to analyze the sample of the patient's blood to get the partial pressure of oxygen and calculate the SpO<sub>2</sub> by use the blood-gas analyzer. This method is inconvenient and discontinuous. For the purpose of measuring the SpO<sub>2</sub> more easily and accurately, our company developed the Pulse Oximeter. The device can measure the pulse rate simultaneously.

The Pulse Oximeter is tiny, and with low power consumption, convenient to use and carry. You just need to put the into the sensor of the device, the SpO<sub>2</sub> value will appear on the screen immediately. In the clinical practice, the tolerance is smaller than  $\pm 2\%$  in the range from 70% to 99%.

The applicant device has low battery voltage alarm function, automatically power of function and data storage function. The power source of the applicant device is 2 AAA alkaline.

The applicant device is not for life-supporting or life-sustaining, not for implant. The device or transducers are not sterile and the transducer is reusable and does not need sterilization or re-sterilization. The device is for prescription. The device does contain drug or biological products.

The device is electrically operated and the Electrical Safety Test and Electromagnetic Compatibility Test following IEC 60601-1 and IEC60601-1-2 were conducted. Please see the

**Attachment 2** Electrical Safety and EMC Test.

The Performance Test reports Low-Voltage Alarm System are presented in **Attachment 3** Performance Bench Test.

The Clinical Test reports following ISO 9919:2005, Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use are conducted in the lab of Beijing Military General Hospital provided in **Attachment 4** Clinical Test Reports.

All applicable standards are listed in **Chapter II** Standards.

The device is not kit.

## 5. Effectiveness and Safety Considerations

### Effectiveness:

The Clinical Test reports following ISO 9919:2005, Medical electrical equipment - Particular requirements for the safety and essential performance of pulse oximeter

The accuracy of CMS-50C pulse oximeter equipment is compliance to the requirement, and the product is safe during the use. It can be used in the clinical environment. It is substantially equivalent to other pulse oximeter product with the same effectiveness and safety.

### Safety Considerations:

The Performance Test reports Low-Voltage Alarm System are presented in **Attachment 3** Performance Bench Test.

The test results of biocompatibility of all the skin-contacting material are presented as **Table IV-2** for the consideration of Biological Specifications. Please see **Appendix 1** Biocompatibility Reports.

The Biological Evaluation Tests are in compliance with the standards of ISO 10993, "Biological Evaluation of Medical Devices". The compatibility of the skin-contact component material in the finished product meets the requirement of Biocompatibility.

The applicant device is compliance with IEC60601-1, Medical electrical equipment - Part 1: General requirements for safety and IEC60601-1-2, Medical electrical equipment - Part 1-2: General requirements for safety -Collateral standard: Electromagnetic compatibility -, Requirements and tests

The Software Validation is in compliance with FDA Guidance to Compliance with FDA Guidance for the Content of PreMarket Submissions for Software Contained in Medical Devices.

## **6. Substantially Equivalence Determination**

### **Comparison Analysis**

The applicant device has same classification information, same indications and intended use, same design principle, similar product design and specifications, same performance effectiveness, performance safety as the predicate device. The only difference is working time Operating temperature, PR display range, Relative humidity, Atmosphere pressure. These differences are slight and do not effluence the effectiveness and safety of the device and don't raise new question of effectiveness and safety.

### **Conclusion:**

The applicant device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the applicant device is determined as safe and effectiveness.



MAY - 5 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Contec Medical System Company, Limited  
C/O Ms. Diana Hong  
Official Correspondent  
Shanghai Mid-Link Business Consulting Company, Limited  
Suite 8D, Zhongxin Zhongshan Mansion  
No.19, Lane 999, Zhong Shan No.2 Road(S)  
Shanghai  
CHINA 200030

Re: K073454  
Trade/Device Name: Pulse Oximeter CMS-50C  
Regulation Number: 21 CFR 870.2700  
Regulation Name: Oximeter  
Regulatory Class: II  
Product Code: DQA  
Dated: April 29, 2008  
Received: April 29, 2008

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K073454

Device Name: Pulse Oximeter CMS-50C

Indications for Use:

The Pulse Oximeter CMS-50C is a non-invasive device intended for the spot-check of oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and the pulse rate of adult and pediatric patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care etc.). This device is not intended for continuous monitoring.

Prescription Use   x    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

Page 1 of   1  

510(k) Number: K073454